



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1067]

Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products--Content and Format; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled "Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." The recommendations in this guidance are intended to assist applicants in developing the "Patient Counseling Information" section of labeling and to help ensure that this section of labeling is clear, useful, informative, and to the extent possible, consistent in content and format. This guidance finalizes the draft guidance issued on September 18, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor. Silver Spring, MD 20993, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in

processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6348, Silver Spring, MD 20993-0002, 301-796-5346; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." This guidance is intended to assist applicants in developing the Patient Counseling Information section of labeling required under 21 CFR 201.57(c)(18). Recommendations include the following: (1) How to decide what topics to include in the section, (2) how to present information within the section, and (3) how to format and organize section contents.

This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the content and format of labeling for human prescription drug and biological products. In the Federal Register of January 24, 2006 (71 FR 3922), FDA published a final rule on labeling for human prescription drug and biological products. The final rule and

additional guidances can be accessed at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm>. The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

This guidance finalizes the draft guidance issued on September 18, 2013 (78 FR 57394). FDA reviewed all received comments carefully during the finalization of the guidance. Other than clarifying edits, no changes of significance were made to the final version of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the content and format of the Patient Counseling Information section of labeling for human prescription drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: December 4, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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